

# **EXHIBIT 52**



Actavis Totowa LLC

## IN-PROCESS TESTING (BLEND SAMPLE) TEST REPORT

Product: Digoxin Tablets, USP 0.25 mg			
MOI #: 145	Revision #: 08	Product ID #: 146	Page 1 of 1
Prepared By: <i>Lamson Murphy</i>	Date: 03/19/07	Approved By: <i>J. Salter</i> 03/27/07	Effective Date: 07/12/07

Batch # 70670A	Theoretical tablet weight: 120.0 mg
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TEST (Source)	SPECIFICATION	RESULT	REFERENCE Volume/Page/ Chemist/Date
Description (In-house):	White to off-white colored slug or free flowing powder	white to off-white free flowing powder	0102/22 AKP 08/16/07
Blend Uniformity (In-house):			0102/22 AKP 08/16/07
Center - Top		92.4 %	
Center - Middle		95.8 %	
Center - Bottom		97.0 %	
Left Slope		95.6 %	
Right Slope		95.1 %	
Left - Middle		94.5 %	
Left - Top		95.2 %	
Right - Middle		94.9 %	
Right - Top		97.8 %	
Front - Middle		94.2 %	
Average:	90.0% - 110.0%	95.2 %	
RSD:	NMT 5.0%	1.5 %	

☒ COMPLIES☐ DOES NOT COMPLY

Reviewed By: <i>JCS</i>
Date: 08/21/07

DATA APPROVAL	
By: <i>J. Salter</i>	Date: 08/22/07

PLAINTIFFS' EXHIBITS 000085

ACTAV 0000492



TOTOWA LLC

## Laboratory Analysis Request Form

Name:	Digoxin Tablet USP 0.25mg				
Identification #:	Pool ID # 146				
Batch/PO/Lot #:	Batch # 706701				
Sample Type: (Specify interval, fill and conditions for stability samples)	Final Blend				
Sample Size/Amount:	As per attached submission form				
Testing Required:	<input checked="" type="checkbox"/> Per Product Specifications <i>in process</i> <input type="checkbox"/> Other (Specify):				
Additional Information/Comments:	N/A				
Requested By:	DR	Date:	08/11/07	Dept:	QA

For QC Use Only			
Sample ID #:	0668		
Issued By:	CDP	Date:	08/11/07
Comments:	30 samples, of final Blend, consists of 3 sets.		

ACTAVIS TOTOWA LLC

Id# 0668

## QA SAMPLE SUBMISSION FORM

Item # N / A Item Name: N / A

IN - PROCESS / FINISHED PRODUCT:

MPR # 14602 - 10 Product : Digoxin Tablets, USP 0.25mgStage: Final Blend ( Set: 1 ) Batch # 70670A

SAMPLE DESCRIPTION: Blender # 36

	TARE Wt.	GROSS Wt.	Net Wt:
1 Center - Top	14978	15297	319 mg
2 Center - Middle	15058	15388	330 mg
3 Center - Bottom	14972	15307	335 mg
4 Left - Slope	15038	15355	317 mg
5 Right - Slope	15053	15350	297 mg
6 Left - Middle	14996	15285	289 mg
7 Left - Top	14962	15310	348 mg
8 Right - Middle	15070	15360	330 mg
9 Right - Top	15017	15302	285 mg
10 Front - Middle	14989	15275	286 mg

Theo. Wt: 120.0 mg

TESTING REQUIRED :

As per in process specification

Submitted BY : DR Date : 08/10/07

Submitted on 9/11/07

QA119.0

PLAINTIFFS' EXHIBITS 000087

Id#0668

ACTAVIS TOTOWA LLC

## QA SAMPLE SUBMISSION FORM

Item # N / A Item Name: N / A

IN - PROCESS / FINISHED PRODUCT:

MPR # 14602 - 10 Product : Digoxin Tablets, USP 0.25mgStage: Final Blend ( Set: 2 ) Batch # 70670A

SAMPLE DESCRIPTION: Blender # 36

	TARE Wt.	GROSS Wt.	Net Wt:	
1 Center - Top	14994	15290	296	mg
2 Center - Middle	15069	15380	311	mg
3 Center - Bottom	15173	15473	300	mg
4 Left - Slope	15047	15360	313	mg
5 Right - Slope	15030	15340	310	mg
6 Left - Middle	15010	15291	281	mg
7 Left - Top	15054	15333	279	mg
8 Right - Middle	14994	15308	314	mg
9 Right - Top	15022	15314	292	mg
10 Front - Middle	15024	15324	300	mg

Sample not tested

Theo. Wt: 120.0 mg

JCS  
08/21/07

TESTING REQUIRED :

As per in process specification

Submitted BY : DR Date : 08/10/07

Shipped on 8/11/07

QA119.0

PLAINTIFFS' EXHIBITS 000088

ACTAVIS TOTOWA LLC

Id#0668

## QA SAMPLE SUBMISSION FORM

Item # N/A Item Name: N/A

IN - PROCESS / FINISHED PRODUCT:

MPR # 14602 - 10 Product : Digoxin Tablets, USP 0.25mgStage: Final Blend ( Set: 3 ) Batch # 70670A

SAMPLE DESCRIPTION: Blender # 36

	TARE Wt.	GROSS Wt.	Net Wt:
1 Center - Top	15144	15450	306 mg
2 Center - Middle	15026	15323	297 mg
3 Center - Bottom	15103	15405	302 mg
4 Left - Slope	14968	15265	297 mg
5 Right - Slope	15083	15392	309 mg
6 Left - Middle	15028	15333	305 mg
7 Left - Top	15030	15329	299 mg
8 Right - Middle	14997	15328	331 mg
9 Right - Top	15087	15380	293 mg
10 Front - Middle	14943	15280	337 mg

Sample not tested

JCS

Theo. Wt: 120.0 mg

08/11/07

TESTING REQUIRED :

As per in process specification

Submitted BY : DR Date : 08/10/07

Submitted on 8/11/07

QA119.0

PLAINTIFFS' EXHIBITS 000089



Actavis Totowa LLC

Department Operating Instruction

TITLE: Evaluation of Laboratory Error

DOI: QC-106

Revision: 04

ATTACHMENT

## LABORATORY ERROR EVALUATION REPORT

Product: Digoxin Tablets, 0.25 mg, USP		Batch/Lot: 70670A	
Laboratory Error Number: LEN 07- 065		Date Initiated: 08/17/07	
Test: Blend Uniformity	MOI/Method: # 145		Rev: # 08
Date Incident Occurred: 08/17/07	Sample: Final Blend (i.e., raw material, in-process, finished product, stability with time/conditions, etc.)		
Instrument ID: HPLC# 14			
Analyst: AKP	Date: 08/17/07	Book: 0102	Page: 22
<b>Background:</b> Analyst was performing blend uniformity test for above batch using MOI# 145, REV# 08. Analyst selected wrong TotalChrom method and sequence for HPLC testing. MOI# 145 having two different methods. For Digoxin Tablets 0.125 mg method ID# 145 and Digoxin Tablets 0.25 mg method ID# 146. Testing was performed according to method ID# 146 and found the results within product specification. Analyst misinterpreted MOI to select the TotalChrom template for method and sequence, instead of ID# 146 template analyst selected ID# 145.			
<b>Action:</b> Analyst was instructed to calculate the results using Quattro-pro program and compare the results obtained from TotalChrom software.			
<b>Conclusion:</b> The results using Quattro-pro program and TotalChrom software were the same and are within product Specifications.			
Analyst: <u>AKP</u> Date: <u>08/21/07</u> Supervisor: <u>ofe</u> Date: <u>08/21/07</u>			
<b>Approval:</b> <input checked="" type="checkbox"/> Evaluation is completed.			
QC Director: <u>[Signature]</u>		Date: <u>08/22/07</u>	